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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,107	LOGTENBERG ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/9/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-10 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Claims 19 and 20 have been added in the Amendment of 9/9/02.

Claims 2, 4, 11-12 are withdrawn from consideration as being drawn to non-elected invention.

Claims 1, 3, 5-10 and 13-20 are pending in the application.

Claims 13-18, presented on the amendment of 3/12/02 are included as pending, since applicants state that these claims are dependent on claim 3. These claims are identical to claims 5, 6, 7, 8, 9 except, as argued, depends on claim 3 instead of claim 1.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-10 and 13-20 are rejected under 35

U.S.C. 112, first paragraph, for the reasons set forth in the last Office action, page 3, paragraph 10.

Response to Arguments

Applicants argue that if the displayed peptides bind the oligopeptides, they would be recognized as binding the target. It is further argued that there is simply no requirement that the actual structure or sequence of the proteinaceous target be recited, or of the oligopeptides derived therefrom or the displayed peptides contacted therewith, be specific for the claim to be clear and enabled. Binding normally occurs for all types or all kinds of compounds, even for those compounds not necessarily required to specifically bind with each other. The ultimate question to ask is which compounds will specifically bind to each other such that the bound compounds can be identified from the limitless numbers of formed complex. (Note the original claims which contain this specific limitation i.e., specific binding). The claim recites for identifying a peptide that (specifically, as originally claimed) binds to a proteinaceous target. If the invention resides only in finding binding between any molecules, then it is not clear where the novelty resides, since all compounds one way or another bind, if not to each other, to a target. Thus, the specification does not provide adequate direction or guidance as to which compound binds to one another and more importantly, how separation of each of the myriads of bound compounds is accomplished.

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Applicants question why if the identity of a peptide that binds is already known, why would the skilled person use a method to identify it as binding? Because, it is only then that one can determine which specific target the peptide specifically binds to. Even for a known peptide, there are literally millions of target the peptide can bind to without necessarily binding to the object or desired target. There is yet, to discover a method by which all types of binding for all types of compounds (specifically peptides) can be assessed. This is a formidable task that still remains to be discovered and is still faced by worker in this art. Thus, the single illustrative embodiments of antibody-antigen as the peptide and target would not suffice as enabling disclosure for the broad claimed invention containing numerous undefined variables. The broad claimed invention is nothing more than an invitation to experiment.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

The following rejection is applicable to the newly amended claims:

Claims 19 and 20 are confusing and inconsistent in the recitation that the proteinaceous target is a protein. Claims 1 and 3 recite for a method by which the target is an oligopeptide derived from protein target. There is no method step recited for a protein as the target. Also, these claims do not further limit the base claim, which already recites that the target is a proteinaceous target.

Claim 3 is rejected under this statute for the reason advanced at page 3, paragraph B of the last Office action. Since applicants have not responded to this rejection, it is believed that applicants are acquiescing therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Barsomian (WO 95/15982) for reasons advanced at page 6, paragraph 18 of the last Office action.

It is argued that this reference completely fails to disclose the synthesis of oligopeptides on a solid phase as required by the claims. However, said synthesis is inherently taught by Barsomian. An antigen or its epitopic peptide attached to a solid support material would indicate that the antigen had undergone synthesis for it to be attached on a solid phase, as the polyacrylamide beads, disclosed by Barsomian at page 30, line 1. [Solid phase synthesis of peptide has advanced so markedly that at present it is now automated. The step-by-step solid phase synthesis process is normally omitted, as evident from page 15, lines 33-35 of the specification, simply relying on the process used by Geysen. Furthermore, the solid phase synthesis, as being a separate step is unclear as to its inclusion in the instant process or any processes of e.g., capture affinity]. Contrary to applicants' assertion, no motivation is required for an anticipatory reference.

Claims 1, 3, 5-10 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruif et al (J. Mol. Biol.) for reasons set forth at pages 7-8, paragraph 20 of the last Office action.

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It is argued that applicants have carefully reviewed the statement of the rejection and submit that no *prima facie* case of obviousness has been presented. The rejection is not an obviousness rejection rather an anticipation (102) rejection.

The same argument under Barsomian is applied herein since applicants presented the same argument i.e., with respect to the solid phase synthesis of the target.

It is of interest to note applicants' arguments that "...solid-phase-bound-antigens" is taught by Kruif and not "antigens which are synthesized on solid-phase". Is this merely a matter of semantic? The claims do not recite for any method step of synthesizing a peptide on a solid-phase occurring simultaneously with the phage display peptide and binding reaction with an antibody. It appears that the antigen has to be bound on the solid phase and then contacted with an antibody for a specific binding assay or determination.

[Identification of peptides from a library usually requires that the target, for affinity enrichment, be covalently attached to the solid phase so as to prevent it from being washed from the solid phase]. [Applicants further arguments that this rejection is contradictory to the rejections under 35 USC, 112 first paragraph is not well taken. Applicants asked how the claimed invention is obvious to a skilled person at the time of

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the invention without the benefit of the instant application, it if was not enabled. Similarly, how can the claimed invention be unclear as to the skilled person if the invention would have been obvious to him/her? As stated above, this is an anticipation rejection not an obviousness rejection. (The alternative obviousness rejection is withdrawn and only the anticipatory rejection is maintained.) Nevertheless, to address applicants' question, a rejection under 112, is different from the anticipation (or obviousness) rejection. The claims are anticipated by the Kruif reference because Kruif discloses specific components such as the antibody displayed on the phage, the antigen as the target and the specific method by which these specific components specifically bind to each other. However, the broad claims, at least claims 1 and 3, do not recite for any kind of peptide displayed on the replicable package or any target for the peptide. And, more importantly for a method of identifying any or all kinds of binding between all the components present in a display phage and a target present in any type of solution. It appears that the claims are unclear in failing to distinctly circumscribe the various claimed variables].

The rejection of the claims over Ladner and Ishikawa are withdrawn.

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No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 2, 4, 11-12 drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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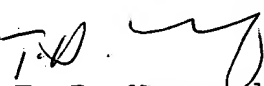
REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 25, 2002